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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,008	07/24/2001	Jeffrey Grayzel	129336-00040	5219

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EXAMINER
BUI, VY Q

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/912,008	Applicant(s) GRAYZEL ET AL.	
	Examiner Vy Q. Bui	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *24-32 and 41-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-23 and 33-40* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

In response to the applicants' request for an examination of claim 45 (see amendment, paper 13, page 6), the examiner would like to bring the applicants attention to restriction paper #5. As indicated in paper #5, non-elected species 2 covers claims about a balloon having continuous stiffening members.

Claim 45 drawn to a non-elected invention (species 2) and therefore is withdrawn from further consideration by the examiner, 37 CFR 1.142(b).

The restriction has been made final.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-2, 4, 8-9, 11-14, 16-20, 23, 33-35, and 37-40 are rejected under 35 U.S.C. 102(e) as being anticipated by VIGIL et al (6,102,904).

As to claims 1-2, 4 and 8-9, VIGIL (Fig. 2-4e and 6) discloses a device for treating a stenosis and dilating a lumen of a blood vessel. VIGIL device comprises balloon 16 or balloon assembly 16/18 of an flexible material such as a polyethylene terephthalate or PET (column 6, lines 56-58), longitudinal stiffening members 20 with base 40 of nickel (column 7, lines 44-45) arranged longitudinally aligned and in a grid pattern along a perimeter of balloon 16 or balloon assembly 16/18. Stiffening members 20 have a geometric shape of a cone (Fig. 4B) or a tubular body (Fig. 4A). As a cone or a tubular body, stiffening members 20 have curved cross-sections.

As to claims 11-14, VIGIL (Figs. 4A-4E) discloses stiffening members 20 including smooth raised surfaces 42/46, and stiffening members 20 are pointed (Figs. 4C-4E) or sharp (Fig. 3A and 7) to pierce/cut an occlusion.

As to claim 16, VIGIL (Fig. 2-3A) shows stiffening members 20 disposed in a central section of balloon 18.

As to claims 17-20, VIGIL (Figs. 2-4E) shows stiffening members 20 comprises raised surfaces 42/46 as means for engaging an occlusion in a lumen or means for piercing an occlusion in a lumen or means for temporarily retaining a stent/stent-graft.

As to claim 23, VIGIL (Figs. 5A-5B) shows stiffening members 20 are disposed on a sheet of material 50.

As to claims 33-35, and 38-39, VIGIL (Fig. 5A-5B) discloses a device for treating a stenosis and dilating a lumen of a blood vessel. VIGIL device comprises balloons 16/18 of an flexible material such as a polyethylene terephthalate or PET (column 6, lines 56-58), longitudinal stiffening members 20 with bases 50 (Fig. 5A-5B) arranged along a perimeter of balloon 18. Stiffening members 20 comprise truncated cones (Fig. 4B) having raised surfaces being substantially pointed/sharp (Fig. 5A) as means for engaging/piercing an occlusion in a lumen of a blood vessel.

As to claim 37, stiffening members 20 are disposed in the central section of balloon 18.

As to claim 40, longitudinal stiffening members 20 disposed on a sheet of material 50 (Fig. 5A-5B).

3. Claims 1 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by SPAHN (3,779,201).

As to claims 1 and 21, SPAHN (Fig. 1-2; column 2, lines 17-22) shows balloon 11 of flexible material such as a plastic (abstract, line 2; claim 1) and 4 stiffening members/ribs 18 disposed longitudinally inside balloon 11 and discontinuous in the middle section of balloon 11 for reinforcing the balloon (column 2, lines 37-46). The stiffening members 18 shown in Fig. 2 as solid hence are less flexible than balloon 11 in longitudinally direction. Stiffening members 18 are located within balloon 11 and abutting the inner surface of balloon 11 (Fig. 2).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 3 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over VIGIL et al (6,102,904) in view of BARATH et al (5,242,397).

As to claims 3 and 22, VIGIL discloses substantially all structural limitations as recited in the claim, except for the stiffening members arranged in a staggered configuration and radio opaque marker. It is well known to provide a radio opaque material on a device such as a stent, a catheter, or a balloon for monitoring the device during deployment inside a patient. For example, BARATH (Fig. 2A) shows stiffening members 10 arranged in a staggered configuration and radio opaque platinum marker 9

for monitoring the location of balloon 1 during deployment inside a patient. In view of BARATH, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrange stiffening members 20 of VIGIL in a staggered configuration and provide a radio opaque marker to one of the stiffening element so as to keep track of the location of the balloon 16/18 during deployment of the balloon inside a patient.

3. Claims 10, 15 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over VIGIL et al (6,102,904) in view of BOOTH et al. (5,653,690).

As to claim 10, VIGIL-'904 does not disclose the stiffening members 20 having a polygonal cross section. However, BOOTH (Fig. 29) shows balloon 240 having stiffening members 244 of a polygonal cross section for retention enhancement (abstract, lines 3-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stiffening members 20 of VIGIL-'904 to have polygonal cross section, as this configuration would provide another suitable configuration for retention enhancement.

As to claims 15 and 36, VIGIL-'904 discloses substantially all structural limitations as recited in the claim, except for a saw-tooth configuration. However, BOOTH (Fig. 28) shows balloon 200 having stiffening members 244 of a saw-tooth configuration for retention enhancement (abstract, lines 3-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stiffening members 20 of VIGIL-'904 to have a saw-tooth configuration, as this configuration would provide another suitable configuration for retention enhancement.

4. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over VIGIL et al (6,102,904)

VIGIL discloses the claimed invention except for the stiffening members overlap or inter-digitate with another one of the stiffening members. It would have been an obvious matter of design choice to provide the VIGIL stiffening members to overlap or inter-digitate to another of the stiffening members, since such a modification would have involved a mere change in the

arrangement and shape of the stiffening members. A change in shape/size of a component is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Allowable Subject Matter

Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

The amendment and remark filed on 7/16/2003 (paper # 13) under 37 CFR 1.131 has been considered but is ineffective to overcome the prior art of reference applied in the previous rejection.

The applicants asserted that as to VIGIL-'904 reference:

1. Dispensers 20 are not "longitudinal stiffening members".

2. Sleeve 18 is not a balloon, therefore dispensers 20 are not disposed along a perimeter of the balloon 18.

3. Dispensers 20 are not suitable to retain a stent or a stent –graft.

In response, the examiner would like to bring the applicants' attention to the following:

1. Each dispenser 20 has a longitudinal length and each does increase the rigidity of balloon assembly 16/18 (see Fig. 3A-5B). Therefore, dispensers 20 are indeed "longitudinal stiffening members".

2. First, sleeve 18 is made of the same polymeric material (PET) as balloon 16 (col. 6, lines 56-58). Sleeve 18 is expanded when the balloon 16 is inflated (col. 13, lines 1-4) or sleeve 18 is expanded when fluid pump 58 shown in Fig. 2 pumps fluid into sleeve 18. Therefore, even sleeve 18 has holes 52 for a treatment fluid to escape, sleeve 18 is indeed a balloon (leaking balloon or balloon having holes).

Second, one of ordinary skill in the art would consider balloon 16 and sleeve 18 as an expandable balloon assembly 16/18 or an expandable balloon 16/18 as a whole.

3. Dispensers 20, especially ones shown in VIGIL Fig. 4B-4E, as compared to Fig. 7a-7G of the instant invention, for example, are quite structurally capable of retaining a stent.

As to SPAHN-'201 reference, the applicants asserted that SPAHN device is not a dilating balloon as recited in the claim 1 and 21 and SPAHN device does not fit inside a person.

In response, the examiner would like to direct the applicants' attention to Fig. 1-4, which clearly show a dilating/inflatable/expandable balloon. In addition, claim 1 and 21 do not require the device to fit into a person.

For the reasons indicated above, the above rejection remains substantially the same as the previous rejection.

Conclusion

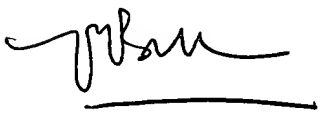
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420 and whose email is vy.bui@uspto.gov. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2708 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB

9/26/2003.